UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/589,288 | 06/08/2000 | Guo-Liang Yu | PF343P3C5 | 1519 |

73326 7590 03/02/2011

Leydig, Voit & Mayer Ltd.
Two Prudential Plaza - Suite 4900
180 North Stetson Avenue
Chicago, IL 60601-6731

| EXAMINER | |
|---|---|
| BUNNER, BRIDGET E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 03/02/2011 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chgpatent@leydig.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/589,288 | YU ET AL. | |
| | Examiner | Art Unit | |
| | Bridget E. Bunner | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *195-207,222-295,297-309,311 and 312* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☒ Claim(s) *207,231,291-294,297-300,309,311 and 312* is/are objected to.

8)☒ Claim(s) *195-207,222-295,297-309,311 and 312* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 July 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/23/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims rejected are 195-206,222-230,232-290,295, 301-308.

## DETAILED ACTION

### Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under Ex Parte Quayle, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 23 September 2010 has been entered.

### Status of Application, Amendments and/or Claims

The amendments of 23 September 2010 and 24 February 2011 have been entered in full. Claims 354-358 are added.

Newly submitted claims 354-358 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

New claims 354-358 recite specific neutrokine-alpha antibodies. The restriction election of 20 February 2001 restricted the originally presented claims into three different groups of inventions (i.e., nucleic acid molecule, protein, and antibody, respectively). Hence, the newly added claims would be included with Invention III, neutrokine-alpha antibodies. In the Response of 20 August 2001, Applicant added new claims directed to a method of using neutrokine-alpha antibodies and indicated these claims as "Group IV". Applicant elected Group IV with traverse. In the Non-Final Rejection of 06 November 2001, the Examiner indicated that the traversal was not found persuasive. Specifically, each of the Groups had a different

classification and required a non-coextensive search of the prior art. It is also noted that the antibody claims of Group III (thus, including the newly added claims 354-358) and the examined claims of Invention IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the antibody can be utilized in in vitro immunoassays or diagnostics.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 354-358 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 195-207, 222-295, 297-309, 311, 312 are pending under consideration in the instant application.

**Claim Objections**

1. Claims 207, 231, 291-294, 297-300, 309, 311, 312 are objected to because of the following informalities:

2. Claims 207, 231, 291-294, 297-300, 309, 311, 312 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Appropriate correction is required.

**Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 195-203, 205, 206, 222, 223, 225-230, 232-240, 242-247, 249-255, 257-263, 265-269, 271, 273-282, 284-290, 295, 301-308 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 and 49-57 of U.S. Patent No. 7,879,328 (Ruben et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to methods of

antagonizing neutokine-alpha in an animal having systemic lupus erthematosus or rheumatoid arthritis comprising administering to said animal an antibody that binds (i) amino acid residues 1-285 of SEQ ID NO: 2 of the instant application or (ii) amino acid residues 134-285 of SEQ ID NO: 2 of the instant application.

Claim 1 of the instant application broadly recites a method of inhibiting B lymphocytes comprising administering an antibody that binds amino acid residues 134-285 of SEQ ID NO: 2. Claim 222 of the instant application broadly recites a method of treating an autoimmune disease or disorder comprising administering an effective amount of an antagonistic antibody that binds a protein consisting of the amino acid sequence of amino acid residues 134-285 of SEQ ID NO: 2. Claim 253 depends from claim 222 and recites that the autoimmune disease or disorder is systemic lupus erythematosus. Claim 281 depends from claim 222 and lists systemic lupus erythematosus as one among the autoimmune diseases or disorders. Claim 229 of the instant application recites a method of treating rheumatoid arthritis comprising administering to an individual an effective amount of an antagonistic antibody that specifically binds a protein consisting of the amino acid sequence of amino acid residues 134-285 of SEQ ID NO: 2. Claim 254 recites a method of treating an autoimmune disease or disorder comprising administering an effective amount of an antagonistic antibody that binds a neutrokine-alpha purified from a cell culture wherein the cells in said cell culture comprise a polynucleotide encoding amino acids 1-285 of SEQ ID NO: 2. Claim 261 depends from claim 254 and recites that the autoimmune disease or disorder is systemic lupus erythematosus. Claim 288 depends from claim 254 and lists systemic lupus erythematosus as one among the autoimmune diseases or disorders. Claim 262 of the instant application recites a method of treating rheumatoid arthritis comprising

administering to an individual an effective amount of an antagonistic antibody that binds a neutrokine-alpha purified from a cell culture wherein the cells in said cell culture comprise a polynucleotide encoding amino acids 1-285 of SEQ ID NO: 2. Claim 301 of the instant application recites a method of treating an autoimmune disease in an animal comprising administering a therapeutically effective amount of an anti-Neutrokine-alpha antibody that binds to human Neutrokine alpha polypeptide having the amino acid sequence of SEQ ID NO: 2.

Claim 1 of the '328 patent recites a method of antagonizing B Lymphocyte Stimulator activity in an animal having systemic lupus erythematosus or rheumatoid arthritis comprising administering to the animal an antibody comprising a first amino acid sequence that is at least 85% identical to amino acid residues 1-123 of SEQ ID NO: 327 and a second amino acid sequence that is at least 85% identical to amino acid residues 141-249 of SEQ ID NO: 327, and wherein the antibody binds B Lymphocyte Stimulator selected from the group consisting of (a) amino acid residues 1-285 of SEQ ID NO: 3228; (b) amino acid residues 134-285 of SEQ ID NO: 3228; and (c) a trimer comprising amino acid residues 134-285 of SEQ ID NO: 3228. Claim 2 of the patent is directed to a method of antagonizing B Lymphocyte Stimulator activity in an human patient having rheumatoid arthritis. Claim 5 of the patent is directed to a method of antagonizing B Lymphocyte Stimulator activity in an human patient having systemic lupus erythematosus. Claim 49 of the ‘328 patent recites a method of antagonizing B Lymphocyte Stimulator activity in a patient having systemic lupus erythematosus or rheumatoid arthritis comprising administering an antibody to the patient wherein the antibody comprises amino acid residues 26-35, 50-66, 99-112, 163-173, 189-195, and 228-238 of SEQ ID NO: 327 and wherein the antibody binds B Lymphocyte Stimulator selected from the group consisting of (a) amino

acid residues 1-285 of SEQ ID NO: 3228; (b) amino acid residues 134-285 of SEQ ID NO: 3228; and (c) a trimer comprising amino acid residues 134-285 of SEQ ID NO: 3228.

Although the instant claims refer to a neutrokine-alpha protein and the claims of the '328 patent refer to a BLyS protein, these are simply two different names for the same protein. Neutrokine-alpha is referred to in the art as THANK, BLyS (B Lymphocyte Stimulator), BAFF, TALL-1, zTNF4, and TNFS13b (see for instance, Groom et al. J Clin Invest 109(1): 59-68, 2002; page 59, bottom of column 1;; Kayagaki et al. Immunity 10:515-524, 2002; page 515, column 1). Additionally, the amino acid sequence of SEQ ID NO: 2 of the instant application is 100% identical to the amino acid sequence of SEQ ID NO: 3228 of the '328 patent. The claims of the instant application are broad in that they recite treating an autoimmune disease or disorder comprising administering an antagonistic antibody that binds a protein comprising (i) amino acid residues 1-285 of SEQ ID NO: 2 or (ii) amino acid residues 134-285 of SEQ ID NO: 2. The claims of the '328 patent are species claims because they recite a specific BLyS antibody to be administered. The specification of the instant application teaches that the antibody compositions may be administered alone or in combination with other agents, such as steroids, antimalarials, methotrexate, gold, pencillamine, anti-TNF antibody, among others (see for example, page 281, [0683] through page 287, [0698]). Furthermore, the specification of the '328 patent teaches that the term "antibody" encompasses not only whole antibody molecules, but also antibody fragments, as well as variants (column 95, lines 45-46). The patent also discloses that antibodies of the invention include monoclonal, multispecific, human, chimeric, Fab fragments, and labeled, among others (column 95, lines 48-54; column 96, lines 4-14, 49-51; column 114, lines13-27; column 126, lines 64-67; column 127, lines 1-65).

The Examiner acknowledges that the instant application is the earlier filed application between the two cases. However, according to MPEP § 804(III)(B)(1)(b), if the patent is the later filed application, the question of whether the timewise extension of the right to exclude granted by a patent is justified or unjustified must be addressed. A two-way test is to be applied only when the applicant could not have filed the claims in a single application and there is administrative delay. See In re Berg, 46 USPQ2d 1226 (Fed. Cir. 1998) ("The two-way exception can only apply when the applicant could not avoid separate filings, and even then, only if the PTO controlled the rates of prosecution to cause the later filed species claims to issue before the claims for a genus in an earlier application . . . In Berg's case, the two applications could have been filed as one, so it is irrelevant to our disposition who actually controlled the respective rates of prosecution."). In the absence of administrative delay, a one-way test is appropriate. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993). Unless the record clearly shows administrative delay by the Office and that applicant could not have avoided filing separate applications, the examiner may use the one-way obviousness determination and shift the burden to applicant to show why a two-way obviousness determination is required.

4. Claims 195-206, 222-228, 236-252, 254-260, 269-290, 301-308 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-6, 9-12, and 21 of copending Application No. 12/170,333.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to the administration of antibodies against

Neutrokine-alpha. The claims of the instant application are broadly directed to a method of inhibiting B lymphocytes (claim 195), a method of inhibiting B lymphocyte proliferation (claims 196, 236, 246), a method of inhibiting B lymphocyte differentiation (claims 197, 236, 246), and a method of inhibiting B lymphocyte survival (claims 236, 246) comprising administering an antibody that binds the Neutrokine-alpha amino acid sequence of SEQ ID NO: 2 or specific fragments thereof. Claims 222 and 254 of the instant application are broadly directed to a method of treating an autoimmune disease or disorder comprising administering an antibody that binds the Neutrokine-alpha amino acid sequence of SEQ ID NO: 2 or specific fragments thereof. Meanwhile, claim 1 of the '333 application is directed to a method of treating or ameliorating a cancer comprising administering to a patient in need thereof an antibody that binds a Neutrokine-alpha polypeptide of SEQ ID NO: 2. It is noted that dependent claims 281 and 288 of the instant application recite that the autoimmune disease or disorder treated is Waldenstrom's macroglobulinaemia and cancer, both of which are encompassed by claims of the '333 application. The specification of the instant application teaches that the antibody compositions may be administered alone or in combination with other agents, such as steroids, chemotherapeutics, growth factors, cytokines, and radiation, among others (see for example, page 281, [0683] through page 289, [0709]). Furthermore, the specification of '333 teaches the same antibody dosages as recited in the claims of the 'instant application (see page 172, [0442] of the '333 application) and that antibodies may be polyclonal, monoclonal, humanized, chimeric, Fab fragments, and Fab' fragments (page 145, [0342-0343]). The specification of '333 also discloses that the antibodies may be labeled (page 160, [0391-0392]). Thus, the claims of the instant application are not patentably distinct over the claims in copending Application No.

12/173,333.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 195-206, 222-295, 297-308 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over:

| | |
|---|---|
| Copending Application No. 12/870,548 | claims 18-19 |
| Copending Application No. 12/870,394 | claims 1-9, 11-13, 15-19 |
| Copending Application No. 12/965,535 | claims 1, 9, 10, 15, 16, 19 |

Although the conflicting claims are not identical, they are not patentably distinct from each other because all sets of claims are directed to the administration of antibodies against Neutrokine-alpha.

Claim 18 of the '548 application recites a method of preventing or treating an autoimmune disease comprising administering an effective amount of an antibody that binds an amino acid sequence comprising residues 134-146 of human Neutrokine-alpha protein (SEQ ID NO: 2). Claim 19 of '548 recites that the autoimmune disease is systemic lupus erythematosus, rheumatoid arthritis, Sjogren's syndrome, autoimmune diabetes, AIDS, or an autoimmune disease associated with B-cell proliferation and immunoglobulin secretion. Furthermore, the specification of '548 teaches the same antibody dosages as recited in the claims of the instant application (see page 172, [0443] of the '548 application) and that antibodies may be polyclonal,

monoclonal, humanized, chimeric, Fab fragments, and Fab' fragments (page 145, [0342-0343]). The specification of '548 also discloses that the antibodies may be labeled (page 160, [0391-0392]).

Claim 1 of the '394 application recites a method of inhibiting the activation of nuclear factor κB in a cancer cell comprising treating the cancer cell with an antibody that binds a Neutrokine-alpha polypeptide of SEQ ID NO: 2. Claims 2 and 6 recite the step of treating the cancer cell with the Neutrokine-alpha antibody in an amount effective to induce radiation sensitivity therein. Claim 9 recites a method of treating, preventing, or ameliorating a cancer comprising administering to a patient in need thereof a Neutrokine-alpha antagonist. Claim 19 recites a method of treating an autoimmune disease in an animal comprising administering a therapeutically effective amount of an antibody that binds to a Neutrokine-alpha polypeptide. Claims 3-4, 7, 11, 12, and 16 recite that the cancer is a B cell cancer. Furthermore, the specification of '394 teaches the same antibody dosages as recited in the claims of the instant application (see page 204, [0442] of the '394 application) and that antibodies may be polyclonal, monoclonal, humanized, chimeric, Fab fragments, and Fab' fragments (pages 171-172, [0342-0343]). The specification of '394 also discloses that the antibodies may be labeled (page 190, [0391-0392]).

Claim 1 of the '535 application broadly recites a method of regulating apoptosis in a cell comprising contacting the cell with an agent capable of neutralizing Neutrokine-alpha, such that an activity of Neutrokine-alpha is inhibited. Claim 16 of '535 recites a method for treating leukemia in a subject, comprising contacting a subject with an agent capable of neutralizing Neutrokine-alpha such that an activity of Neutrokine alpha is inhibited. Claims 10 and 19 recite

that the agent is an antibody. The specification of '535 teaches the same antibody dosages as recited in the claims of the instant application (see page 254, [0493] of the '535 application) and that antibodies may be polyclonal, monoclonal, humanized, chimeric, Fab fragments, and Fab' fragments (pages 212-213, [0386-0387]). The specification of '535 also discloses that the antibodies may be labeled (pages 233-234, [0434-0435]).

The claims of the instant application are broadly directed to a method of inhibiting B lymphocytes (claim 195), a method of inhibiting B lymphocyte proliferation (claims 196, 236, 246), a method of inhibiting B lymphocyte differentiation (claims 197, 236, 246), and a method of inhibiting B lymphocyte survival (claims 236, 246) comprising administering an antibody that binds the Neutrokine-alpha amino acid sequence of SEQ ID NO: 2 or specific fragments thereof. Claims 222 and 254 of the instant application are broadly directed to a method of treating an autoimmune disease or disorder comprising administering an antibody that binds the Neutrokine-alpha amino acid sequence of SEQ ID NO: 2 or specific fragments thereof. Dependent claims 281 and 288 of the instant application recite that the autoimmune disease or disorder treated is Waldenstrom's macroglobulinaemia and cancer. The specification of the instant application teaches that the antibody compositions may be administered alone or in combination with other agents, such as steroids, chemotherapeutics, growth factors, cytokines, and radiation, among others (see for example, page 281, [0683] through page 289, [0709]).

These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

6. Claims 195-206, 222-295, 297-308 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4, 5, 14, 18-21, 24, 35-39, 41, 45-48, 51, 52 of copending Application No. 12/952,091 in view of Weth, G. (U.S. Patent 5,589,499).

It is noted that Neutrokine-alpha is referred to in the art as THANK, BLyS (B Lymphocyte Stimulator), BAFF, TALL-1, zTNF4, and TNFS13b (see for instance, Groom et al. J Clin Invest 109(1): 59-68, 2002; page 59, bottom of column 1;; Kayagaki et al. Immunity 10:515-524, 2002; page 515, column 1).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets both sets of claims encompass the administration of antibodies that bind Neutrokine-alpha. Claims 4, 5, and 35-37 of the '091 application broadly recite a method for treating a subject suffering from a disease comprising the steps of (1) administering a therapeutic agent to the subject, (2) determining the serum BAFF/BLyS levels in a test sample of the subject, (3) administering a therapeutically effective amount of the same or different therapeutic agent at a time point dependent on the serum BAFF/BlyS level in the subject. Claims 14 and 41 of '091 recite that the therapeutic agent binds BAFF/BLyS. Meanwhile, the claims of the instant application are directed to a method of inhibiting B lymphocytes (claim 195), a method of inhibiting B lymphocyte proliferation (claims 196, 236, 246), a method of inhibiting B lymphocyte differentiation (claims 197, 236, 246), and a method of inhibiting B lymphocyte survival (claims 236, 246) comprising administering an antibody that binds the Neutrokine-alpha amino acid sequence of SEQ ID NO: 2 or specific fragments thereof. Claims 222 and 254 of the instant application are directed to a method of treating an autoimmune disease

or disorder comprising administering an antibody that binds the Neutrokine-alpha amino acid sequence of SEQ ID NO: 2 or specific fragments thereof. Thus, the claims of the '091 are genus claims while the claims of the instant application are species claims. It is also noted that the specification of '091 teaches the same dosages as recited in the claims of the instant application (see page 254, [0493] of the '091 application)) and that antibodies that bind Neutrokine-alpha (BAFF/BLyS) may be polyclonal, monoclonal, humanized, chimeric, Fab fragments, and Fab' fragments (pages 212-213, [0386-0387]). The specification of '091 also discloses that the antibodies may be labeled (pages 233-234, [0434-0435]).

Although the instant claims do not include a specific step wherein Neutrokine-alpha levels are monitored during treatment, the instant specification discloses that biological samples obtained from a subject may be analyzed for the expression levels of Neutrokine-alpha (pages 233-234, [0503-0504; page 237, [0510-0512]). It was also well known in the prior art as evidenced by Weth (U.S. Patent 5,589,499) that levels of proteins of interest may be measured before or after the administration of therapeutic agents (see claims of '499 patent). It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the anti-Neutrokine-alpha antibody administration methods of the instant application by adding steps to determine the levels of Neutrokine-alpha in the subject as taught by the instant specification, Weth et al., and common knowledge in the art. The person of ordinary skill in the art would have been motivated to make that modification to monitor the effects of the administration of therapeutic agent. The person of ordinary skill in the art reasonably would have expected success because similar methods were already being performed at the time the

invention was made. Therefore, the claims of the instant application are not patentably distinct over the claims in copending Application No. 12/952,091.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

## Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB
Art Unit 1647
22 February 2011

/Bridget E Bunner/
Primary Examiner, Art Unit 1647